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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,824	08/10/2001	William Gavin	10275-146001 / TCI-146	6238

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GTC BIOTHERAPEUTICS, INC.
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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/927,824

Applicant(s)
Gavin et al.

Examiner
Vera Afremova

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1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 19, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 8-14, and 16-44 is/are pending in the application.
- 4a) Of the above, claim(s) 34-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 8-14, and 16-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Status of claims

Claims 1, 3-6, 8-14, 16-26 as amended and new claims 27-44 [Paper No. 9 filed on 5/19/2003] are pending and subject to restriction requirement.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-6, 8-14, 16-26 as amended and new claims 27-27-33, drawn to a method, classified in class 435, subclass 374, for example.
- II. New claims 34-44, drawn to a sperm cryoprotectant solution comprising egg yolk, fructose, citric acid, Tris buffer and antibiotics, classified in class 435, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if **either or** both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product or sperm, for example: extender of US 3,940,943 which comprises lactose and egg yolk (col. 2, last two lines to col. 3, lines 1-2). The inventions above are independent and distinct, each from the other. They have acquired a separate status in the art

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as a separate subject for inventive effect and require independent searches (as indicated by different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or make obvious the other group. For these reasons restriction for examination purposes is proper.

Newly submitted claims 33-44 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons above. Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 3-6, 8-14, 16-26 as amended and new claims 27-33 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

New claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite because it is limited to the exclusion of glycerol from solutions in the method of preserving sperm wherein the method appears to encompass the use of glycerol since the cooling step a) requires adjustment of temperature with regard to glycerol toxicity.

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Claim Rejections - 35 USC § 102

Claim rejection under 35 U.S.C. 102(b) as being anticipated by SU 986411 [IDS-AL] has been withdrawn because the cited patent does not disclose the use of antibiotics in solutions in a method of preserving mammalian sperm as required by the presently amended claims.

Claim rejection under 35 U.S.C. 102(b) as being anticipated by US 3,940,943 [IDS-AA] has been withdrawn because the cited patent does not disclose the use of antibiotics in solutions in a method of preserving mammalian sperm as required by the presently amended claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-6, 8-14, 16-26 as amended and new claims 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU 986411 [IDS-AL] and US 3,940,943 [IDS-AA] taken with Royere et al. [IDS-AQ], US 3,791,384 [IDS-AB] and Ahmad et al. [U].

Claims are directed a method of preserving mammalian sperm and storing the sperm wherein the method encompasses step of slow cooling to a first temperature of about 2°C to about 10° C , step of rapid freezing at second temperature of about -60°C to about -90° C of the sperm and the use of cryoprotectant buffers without glycerol for cooling the sperm and with glycerol for treating the sperm before freezing. The first solution (cooling stage to first temperature) does not contain glycerol, the second solution (added before freezing) contains

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glycerol and antibiotics. The sperm is hold at first temperature for 4-21 hours. Some claims are further drawn to the use of 5-10% glycerol in the second solution. Some claims are further drawn to exclusion of glycerol from cryoprotectant buffer. Some claims are further drawn to the use of cryoprotectant buffer comprising egg yolk at concentration of 10-30 %. Some claims are/are further drawn to freezing the cooled sample by maintaining the cooled sample at the second temperature for 7-20 minutes or 10-15 minutes. Some claims are further drawn to the use of cryoprotectant solution with Tris buffer, fructose and citric acid. Some claims are further drawn to a method of making an animal by fertilizing an oocyte with the preserved sperm.

SU 986411 discloses a method of preserving mammalian or bovine sperm wherein the method comprises step of combining the sperm with a first typical cryoprotectant buffer containing egg yolk (col. 3, line 18), step of cooling the sperm to a first temperature of about 4 using a slow cooling rate of about 0.2°C to 0.5°C per minute over the corse of about 3-3.5 hours (table 1), step of adding a second cryoprotectant buffer comprising 10% glycerol (col. 3, line 45), step of maintaining the cooled sperm with the glycerol containing cryoprotectant buffer for 30 minutes at about 4°C to 5°C (English abstract, col. 3, last line and col. 4, line 7), step of freezing sperm in vapors of liquid nitrogen by maintaining or holding at second temperature of about -120° C to about -160°C for 8-8.5 minutes (col. 3, lines 8-10 and col. 4, lines 13-16) and step of storing the sperm in liquid nitrogen or at the third temperature (col. 4, line 25). The cited SU 986411 teaches step of freezing the sperm at “freezing” temperature for about 8-8.5 minutes (English abstract or col. 3, lines 9-10 or col. 4, lines 12-16) what is within the claimed ranges of

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7-20 minutes intended for freezing/maintaining step. Further, the freezing of the sperm sample down to the level of temperature of the liquid nitrogen vapors of about -120°C to about -140°C as disclosed by the cited SU will necessarily utilize the temperatures which are above the liquid nitrogen temperatures including from -40°C to about -100°C or from -60°C to about -90°C as required by the present claims 10 and 13 for at least some period of time. The cryoprotectant solutions in the cited method comprises fructose and egg yolk (col. 3, lines 16-17). Furthermore, the cited patent SU 986411 discloses steps of thawing the frozen sperm and using the stored sperm for oocyte fertilization (col. 4, line 47), thereby making an animal within the meaning of the presently claimed invention. Thus, the cited SU teaches the same or similar active steps in the method for preserving mammalian sperm as the claimed method.

US 3,940,943 discloses a method of preserving sperm encompassing the use of stepwise cooling and/or freezing the sperm (col. 2, lines 33-35) wherein the method does not require the use of glycerol (col. 2, line 41). The disclosed method comprises step of combining sperm with a typical cryoprotectant buffer containing 25% egg yolk (col. 3, line 1), step of cooling the sperm with a slow cooling rate less than 1°C per minute to the temperature of about 3°C to about 8°C (col. 3, lines 20-22), step of holding the cooled sperm sample from 30 minutes to several hours (col. 3, line 24), step of rapid freezing the sperm to a second temperature of about -4°C to about -100°C (col. 3, lines 49-50) and step of storing the sperm in liquid nitrogen (col. 3, line 64). The cited patent US 3,940,943 further discloses thawing the frozen sperm (col. 4, lines 1-5) and using the preserved sperm for oocyte fertilization (col. 5, line 39), thereby making an animal within the

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meaning of the presently claimed invention. The cited method comprises step of cooling or holding the sperm at "first" temperature of about 3°C to 8°C for about 30 minutes to several hours including 4 hours (col. 3, lines 26-28). Thus, the cited US 3940943 teaches the same or similar active steps in the method for preserving mammalian sperm. It also teaches various cryoprotectant compositions including egg yolk, which provides buffering effects, and sugar in the cryopreservation solution (lines bridging col. 2 and col. 3), it also teaches other commonly used cryoprotecting diluents with Tris buffer (col.1, lines 37-41).

Both cited patents SU 986411 and US 3,940,943 are relied upon as explained above for the disclosure of methods for preservation of mammalian sperm by protocols encompassing slow cooling and rapid freezing of the sperm diluted in cryoprotectant buffers wherein the cooling/freezing rates as disclosed by the cited patents are within the ranges which are presently claimed. Both cited patents SU 986411 and US 3,940,943 disclose thawing of frozen sperm and fertilizing oocyte with the stored sperm, thereby practicing methods of making animals within the scope of the presently claimed invention. In addition, the reference by Royere et al. confirms the beneficial effects of using slow cooling and rapid freezing stages (page 557, col.1, lines 1-4) and further thawing at 37°C (page 557, col. 1) in the methods for mammalian sperm preservation and further fertilization which are taught by both cited patents SU 986411 and US 3,940,943. The cited reference by Royere et al. teaches that the optimal concentration of glycerol is about 7.5% for preserving mammalian sperm (page 556, col.1, lines 1-3) and it also teaches the concept of

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reducing possible toxic effects of glycerol by adding glycerol to the cooled sperm sample before freezing (page 556, col. 2, lines 8-10).

The cited SU 986411 teaches the steps of cooling including step of maintaining the sperm sample at temperature of 4°C to 5°C for 30 minutes with glycerol but it is lacking particular disclosure with regard to a longer period of holding for several hours including 4-21 hours before addition of glycerol or before freezing. However, the cited US 3,940,943 teaches that at the stage of cooling/maintaining at first temperature the cooled sperm samples might be held from 30 minutes to several hours in order to optimize the cooling and/or packaging procedures in the method for sperm preservation (col. 3, lines 22-26).

The cited SU 986411 teaches the step of rapid freezing by maintaining the sperm sample mixed with non-toxic concentration of glycerol at temperature of about -120°C to -140°C for a short period of 8-8.5 minutes before storing the frozen sperm in liquid nitrogen. But it is lacking a particular disclosure with regard to freezing by maintaining the sperm at -60°C to -90°C for 7-20 minutes or 10-15 minutes. However, the cited US 3,940,943 teaches the rapid freezing of sperm by maintaining the sperm at the lower temperature that in the method of SU 986411 such as between -4°C to -100°C , what is within the presently claimed range. The time of exposure to the temperature between -4°C to -100°C in the method of US 3,940,943 is about 3-10 minutes since the freezing rates are from $10^{\circ}\text{C}/\text{min}$ to $30^{\circ}\text{C}/\text{min}$ as disclosed in US 3,940,943 (col. 3, lines 49-56) what is within the presently claimed range. Thus, the cited US 3,940,943 teaches a decrease in freezing temperatures for the freezing/maintaining step in the method for

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mammalian sperm preservation. The cited US 3,940,943 also teaches that the optimum for the rapid freezing step might be modified depending on packaging type and sample volume (col. 3, lines 52-53). The cited US 3,940,943 also teaches that the sperm samples should be maintained for a sufficient time to allow the stabilization of membrane permeability and osmotic pressure alterations at the initial freezing temperatures (col. 3, lines 39-42).

With respect to the cryoprotectant compositions in the method for sperm preservation, the cited SU 986411 clearly teaches the use of glycerol by adding glycerol before freezing to the cooled sperm diluted in a conventional cryoprotectant buffer comprising egg yolks and fructose. But it is silent with regard to egg yolk concentration in a typical or conventional formulation. However, US 3,940,943 indicates that a typical formulation of a cryoprotectant buffer comprises egg yolk at a concentration of 25 % in the method for mammalian sperm preservation (col. 3, line 1).

But the both cited patents SU 986411 and US 3940943 are lacking disclosure related to the use of antibiotics, citric acid and Tris buffer in the solutions in methods of preserving mammalian sperm. Although the cited SU 986411 teaches the use of fructose in cryoprotectant composition but it is also silent with regard to a particular concentration of fructose in the cryoprotectant composition.

However, it is known to use antibiotics in the composition intended for cold storage and/or freezing of mammalian sperm. For example: US 3,791,384 teaches a method for preserving mammalian sperm wherein the cryoprotectant solution intended for sperm deep

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freezing comprises egg-yolk, glycerol and antibiotics including streptomycin, for example: col. 5, line 23 and line 28. The cited patent US 3,791,384 also teaches the use of other components in composition/solution for sperm preservation including Tris buffer, fructose and citric acid wherein concentration ranges components are within the presently claimed ranges (col. 2, lines 24-29 and from col. 2, lines 65-68 to col.3, line 1-4), for example: 12.5% egg yolk (25 ml for 200 ml of water), about 1.25 % fructose (2.5 g for 200 ml of water), about 1.75% of citric acid (3,46 g for 200 ml of water).

The reference by Ahmad et al. [U] is relied upon to demonstrate the use of antibiotics tylosin, lincospectin and gentamicin in the solutions in the methods for preserving mammalian sperm (see abstract).

Therefore, it would have been obvious at the time the claimed invention was made to practice a mammalian sperm preservation method encompassing the use of slow cooling/rapid freezing of sperm and the addition of glycerol to the cooled sperm before freezing with a reasonably expectation in success for preserving the sperm intended for fertilization because substantially similar protocols have been taught and suggested in the prior art as adequately demonstrated by all cited references {SU 986411; US 3,940,943; Royere et al.}. One of skill in the art would have been motivated to use typical cryoprotectant buffer formulations with egg yolks and glycerol for the expected benefits of sperm preservation intended for fertilization as demonstrated in the prior art {SU 986411; US 3,940,943; Royere et al.}. One of skill in the art would have been motivated to add glycerol to the cooled sperm sample before freezing for the

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expected benefits in reducing possible toxic effects of glycerol on mammalian sperm {SU 986411; Royere et al.}. One of skill in the art would have been motivated to increase or to modify the time for holding sperm samples at first cooling temperature and/or at second freezing temperature in order to optimize cooling/freezing and packaging procedures as suggested by the prior art {US 3,940,943}. One of skill in the art would have been motivated to maintain the sperm samples at the initial or at the low freezing temperature in order to stabilize membrane permeability and osmotic pressure alterations induced by freezing as suggested by the prior art {US 3,940,943}. It would have been obvious at the time the claimed invention was made to add antibiotics and/or other components including Tris buffer and citric acid the cryoprotectant solutions intended for sperm preservation since all presently claimed ingredients are known and have been used for sperm preservation as adequately demonstrated by the cited references US 3,791,384 and Ahmad et al. [U]. The presently claimed concentrations of each and all components are within the concentration ranges used in the prior art in the methods for preserving mammalian sperm as adequately demonstrated by US 3,791,384, for example.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Although the claim 24 is directed to a particular sequence of steps, the prior art teaches the similar sequence of steps including substantially similar, if not identical, limitations with regard to cryoprotectant buffer components, temperatures and time of exposure to cooling/freezing temperatures. Thus, the claim 24 is not considered to encompass any particular

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differences which would distinguish the claimed sequence of steps from the prior art sequences of steps in the methods for sperm preservation comprising slow cooling/rapid freezing of the sperm and the use of cryoprotectant buffer with non-toxic glycerol concentrations after sperm cooling but before sperm freezing as demonstrated by the cited references combined.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 5/19/2003 have been fully considered but they are not persuasive.

With regard to the claim rejection under 35 USC § 103 applicants appear to admit that SU 986411 teaches a method similar to the presently claimed method (response page 16).

However, the applicants' main argument is drawn to the idea of a novelty of a "cryoprotectant buffer solution" of the present invention for optimization of the method for sperm preservation. Yet the claimed method is not limited to the use of any particular cryoprotectant buffer solution. For example: claim 1 does not indicate the use of "cryoprotectant buffer" solution and the only compound in the "solution" as claimed is an antibiotic which is not a cryoprotectant agent. Thus, the method of the cited SU 986411 which is drawn to the addition of glycerol (cryoprotectant agent) before freezing step but after cooling step is considered to be similar to the presently claimed method which encompasses the addition of glycerol

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(cryoprotectant agent) before freezing step but after cooling step. With respect to the claim 13 which indicates the use of a generic “cryoprotectant” solution, the method of the cited SU 986411 is considered to be similar to the presently claimed method because it teaches the use of “cryoprotectant” solution comprising fructose (cryoprotectant agent) for both cooling and freezing steps and it also teaches the use of “cryoprotectant” solution comprising fructose and glycerol for the freezing step. Thus, the method of claim 13 is not limited to any specific and/or different components within the “cryoprotectant buffer” solution as argued which would distinguish over the method of the cited reference. Incorporation of antibiotics in the method of claim 13 is not considered to provide for optimization of cryoprotective effects which are presently argued. Although the claim 22 literally indicates “cryoprotectant” buffer, the claimed method is limited to the sole use of glycerol as a cryoprotectant agent. Thus, the method of the cited SU 986411 which is drawn to the addition of glycerol (cryoprotectant agent) before freezing step but after cooling step is considered to be similar to the presently claimed method which encompasses the addition of glycerol (cryoprotectant agent) before freezing step but after cooling step. New claim 27 indicates the use of fructose but it does not exclude the use of glycerol, and, thus, the presently claimed method is similar to the method of SU 986411 which comprises application of both fructose and glycerol in the method for sperm preservation. New claim 28 is either indefinite or it is drawn to the method similar to the method of the cited US 3940943 which does not require glycerol in the method for sperm preservation.

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Some of the applicants' arguments are drawn to the criticality of the limitation such as time period of "4-21 hours" for maintaining a sample with cooled sperm. Applicants appear to argue that this holding/maintaining time for 4-21 hours is needed to equilibrate glycerol and sperm before freezing (response page 17, par. 1). Yet, the claimed invention is not so limited. For example: claim 1 indicates the use of a time period for 4-21 hours before the addition of glycerol. Thus, the claimed time period does not appear to be intended for equilibration of glycerol and sperm as argued. Further, claims 13, 27 and 28 are drawn to the method which is not limited to the use of glycerol for sperm preservation. Claims 14 and 22 are drawn to the methods which combine both elements such as glycerol and time period of 4-21 hours, however glycerol is added to the sperm sample at different stages and at different temperatures in the methods as claimed. Thus, the concept of using a particular time such as 4-21 hours for equilibration of sperm with glycerol as a sole cryoprotectant agent either is not within the meaning of the claimed invention as the whole or this concept appears to relate to the cryoprotectant agent different from glycerol. The applicants' particular disclosure is uncertain. The example 2 (page 21) does not indicate the equilibration time for 4-21 hours for glycerol and sperm. The example 1 (page 19) indicates time 4-21 hours but it is unclear what cryoprotecting agents have been added and when. Therefore, the cited prior art is still considered to teach and/or suggest the similar concept of using a similar time period to equilibrate sperm and cryoprotectant agent. For example: SU 986411 discloses time periods to equilibrate sperm with cryoprotectant compositions for about 3-3,5 hours before addition of glycerol and for 30 minutes after addition of glycerol wherein the

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cryoprotectant compositions include fructose. US 3940942 discloses time period to equilibrate sperm with a cryoprotectant composition from 30 minutes to several hours wherein the cryoprotectant composition does not include glycerol but includes sugar.

In response to applicants' argument based upon the age of the references US 3940943 (Sikes et al), contentions that the reference patent is old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

With regard to the cited reference by Royere et al applicants appear to argue that it does not teach the cryoprotectant composition provided by the current invention and that it does not teach a stepwise sperm cooling process. This is not found persuasive. The cited references teaches the use of various sperm extenders in the method for sperm preservation including extenders with the presently claimed components such as egg-yolk, fructose, citrate, buffers and glycerol (page 556). The cited reference also teaches the stepwise sperm preservation method comprising slow cooling and rapid freezing (page 557, col. 1, lines 1-4) as encompassed by the presently claimed invention.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

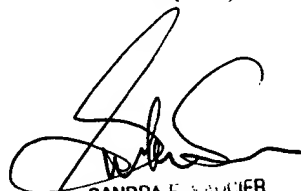
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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August 7, 2003



SANDRA E. SAUCIER
PRIMARY EXAMINER